K121853

510(k) Summary

Date Summary Prepared: June 22, 2012

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510(k) Owner Information: Defibtech, LLC
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Trade (Proprietary) Name: DDU-2400/2450 Semiautomatic External Defibrillator
Common Name: Semiautomatic External Defibrillator
Classification Name: Automated External Defibrillator (21 CFR 870.5310, Product Code MKJ)

Substantial Equivalence Model

The DDU-2400 and DDU-2450 products (DDU-2400/2450) represent modifications to the currently cleared Defibtech DDU-2300 AED. The DDU-2400/2450 is substantially equivalent to the DDU-2300 AED (K081259), with the exception of the optional ECG display/monitoring and manual override features that appear in the DDU-2400/2450 products. These features are substantially equivalent to the Heartstart FR2 AED. The defibrillation waveforms and energy used in manual mode are substantially equivalent to the Heartstart XLT Defibrillator/Monitor.

Proprietary Name	Manufacturer	510(k) Number
DDU-2300 Semiautomatic External Defibrillator	Defibtech, LLC	K081259
Heartstart FR2 AED	Philips Medical Systems	K013425
Heartstart XLT Defibrillator/Monitor	Agilent Technologies, Inc	K992543

The design and intended use of the DDU-2400/2450 AED is substantially equivalent in performance and safety to the devices listed above.

Device Description

The DDU-2400/2450 is a portable, Automated External Defibrillator (AED) intended for use on victims of sudden cardiac arrest (SCA). It is powered by a user-replaceable non-rechargeable battery and supports both adult and pediatric user-replaceable single-use defibrillation/monitoring pads.

The default mode of operation for the DDU-2400/2450 AED is Semiautomatic External Defibrillator (AED mode). In AED mode, after applying the defibrillation pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and, if needed, advises the operator to push the button and deliver a shock. The AED guides the operator through the rescue protocol using a combination of voice and text prompts, audible alerts, and visible indicators. The LCD display shows instructional videos and text prompts.

The DDU-2400/2450 provides some optional features for the advanced user. When used in AED mode, the user can set the LCD display to show the patient's ECG trace. These models also provide a non-diagnostic ECG monitoring mode to allow for rhythm and heart rate monitoring using an optional 3-wire monitoring pads adaptor with standard ECG electrodes.

The DDU-2400 (only) supports a Manual override mode. Manual mode permits the user to override the AED features of the defibrillator. Manual mode is intended for use by personnel trained in ECG recognition who want to use the defibrillator to deliver a shock independent of AED mode. Manual mode provides a display of the patient's ECG trace, operator-selected energy level along with charge, shock, and disarm functions.

The DDU-2400/2450 has a compact design and offers an easy-to-understand user interface with an LCD display. Voice prompts and a graphical user interface provide simple instructions for the operator. The DDU-2400/2450 AED is capable of recording event information including ECG, audio data and SHOCK/NO SHOCK recommendations.

Intended Use

The DDU-2400/2450 Semiautomatic External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:

- Unconscious and unresponsive
- Not breathing

For patients under 8 years old, or less than 55 (25kg), use child/infant electrode pads. Do not delay therapy to determine exact age or weight.

The DDU-2400/2450 AED must be used by or on the order of a physician.

Comparison of Technology Characteristics

The DDU-2400 and DDU-2450 represent modifications to the currently cleared Defibtech DDU-2300 AED, (K081259). They share a common hardware and software platform and employ the same cardiac rhythm analysis algorithm and defibrillation energy and waveform when used as an AED. The modifications provide some optional features for the advanced user such as ECG display, 3-wire ECG monitoring and Manual override, which are substantially equivalent to the Heartstart FR2 AED. The selectable energy and waveforms used in Manual mode are substantially equivalent to waveforms used by the Heartstart XLT.

Performance testing

The DDU-2400/2450 AED uses similar technologies to provide functionally equivalent performance characteristics as the predicate device. Testing demonstrates that the DDU-2400/2450 meets functional and performance specifications, and safety testing assures compliance with applicable industry safety standards.

Conclusion Summary of Safety and Effectiveness

Testing and performance evaluations demonstrate that the Defibtech DDU-2400/2450 AED is substantially equivalent to the predicate devices. The introduction of the DDU-2400/2450 AED does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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Defibtech LLC
c/o Mr. Ed Horton
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Guilford, CT 06437

Re: K121853
Trade/Device Name: DDU-2400/2450 Semiautomatic External Defibrillator and Accessories
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: November 23, 2012
Received: November 28, 2012

Dear Mr. Horton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K121853

Device Name: DDU-2400/2450 Semiautomatic External Defibrillator and Accessories

Indications for Use:

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The DDU-2400/2450 AED must be used by or on the order of a physician.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121853